

**BEFORE THE TENNESSEE
HEALTH SERVICES AND DEVELOPMENT AGENCY
Nashville, Tennessee**

IN RE:)	
)	
EAST TENNESSEE RADIATION)	Docket No. 25.00-115208J
THERAPY SERVICES)	
CN1108-030)	

**COVENANT HEALTH'S RESPONSE
IN OPPOSITION TO PETITION FOR REVIEW**

In December 2011, by a close vote of 5-4, the HSDA granted a Certificate of Need to East Tennessee Radiation Therapy Services ("ETRTS") to provide conventional radiation therapy services in Knoxville. Covenant Health initiated a contested case so ETRTS' application and related claims could be more extensively scrutinized. The case was assigned to Thomas G. Stovall, the Director of the Administrative Procedures Division (i.e., the chief Administrative Judge) and one of the most experienced Administrative Judges in Tennessee. The contested case took more than a year to complete. Extensive discovery was taken under oath and thousands of documents were exchanged by the parties. The trial, which took place over several weeks in January 2013, included testimony from 15 witnesses and the introduction of approximately 200 exhibits. At the trial, ETRTS offered evidence and argument about all the reasons it believed the project should be approved, including testimony by the project's owners and expert witnesses, such as a health planning expert. On May 30, 2013, after hearing all the evidence from both parties and considering oral and written arguments, Judge Stovall issued a 27-page Initial Order, carefully assessing all of the facts and argument under the applicable law and determining that the CON should be denied.

Now, ETRTS asks the Agency to re-open this matter and to conduct yet another hearing about the project. The Agency is not obligated to undertake such an extraordinary and

unnecessary review. Rather, it is entirely within the Agency's discretion whether to grant or to deny the request that this matter be considered again by the HSDA. If the Agency declines to conduct another review, then the Initial Order will become a Final Order. At that time, if ETRTS remains dissatisfied, it has the opportunity to seek further review of the Order in Chancery Court.

Covenant respectfully urges the Agency to deny the petition for an appeal. The HSDA's discretion to review an Administrative Judge's Initial Order should be exercised only in unusual or extreme circumstances. Moreover, it is simply not practical for the Agency to conduct a meaningful review of the thousands of pages of testimony, extensive expert reports and hundreds of exhibits that underlie the Initial Order in this case. For those rare CON applications that give rise to contested cases, that process provides an opportunity for a more careful examination of the claims about a project. The Administrative Judge has more time than the Agency and the opportunity to evaluate testimony taken under oath and subject to vigorous cross-examination. The Administrative Judge can look behind an applicant's claims to see if they are grounded in truth and the law. The purpose of contested cases would be undermined if the outcome of every contested case were to be reviewed by the HSDA. It is difficult if not impossible for the Agency, in the course of one day's meeting, to conduct a meaningful and legally-sufficient review of a year-long contested case conducted by a seasoned Judge. The HSDA should avoid such a time-consuming, costly and practically unworkable review by denying the ETRTS petition.

PROCEDURAL HISTORY

The Parties

Covenant Health is a non-profit corporation with its principal offices in Knoxville. Covenant operates hospitals, cancer centers, and other health care facilities, and engages in many other health care related activities. As the largest TennCare provider in East Tennessee, and one

of the largest in the State, Covenant plays an essential role in supporting the TennCare program.¹ Covenant also owns the Thompson Cancer Survival Centers, which consist of 10 locations across East Tennessee. In addition to offering comprehensive cancer care to more patients in East Tennessee than any other provider, Thompson also provides many free and highly-subsidized community cancer services and resources. Moreover, Thompson has sponsored extensive original research, produced numerous peer-reviewed publications and has for many years maintained a nationally-recognized training program for medical physicists in collaboration with the University of Tennessee.

The applicant, ETRTS, a subsidiary of Provision Healthcare, seeks a CON to initiate conventional radiation therapy services at the Dowell Springs Office Park in Knoxville, Tennessee. In the mid- to late-2000s, a Provision entity controlled by Terry Douglass, Ph.D acquired land at the Office Park. Two physician groups—Tennessee Cancer Specialists and Knoxville Comprehensive Breast Center (“KCBC”) —subsequently decided to locate outpatient offices there.² Other medical tenants in the Office Park include a diagnostic imaging center (owned by an entity associated with Dr. Douglass) and a wellness center. In 2008-2009, before filing any application for a CON, Provision spent approximately \$1 million to build two linear accelerator vaults inside a building in the Dowell Springs Office Park.

Provision’s First CON Application (July 2009)

In July 2009, after the decision of the two physician groups to open offices at Dowell Springs and after it had already built vaults for two linear accelerators, Provision filed its first application for a CON seeking approval to initiate radiation therapy services. The Agency

¹ From 2006 through 2010, Covenant provided more than \$722 million in uncompensated care to TennCare, Medicare and charity patients

² The doctors’ decision to open these offices coincided with the decision of two of their partners to invest in new medical office buildings at the Office Park.

considered Provision's first application on December 16, 2009. Covenant and other area providers opposed the application, pointing out that there was no need for a new provider under the State Health Plan, that patient convenience would not be served and that multiple nonprofit cancer centers and hospitals would be harmed by the approval of unnecessary, duplicative services aimed at undermining profitable service lines. The HSDA denied Provision's 2009 application by a 6-1 vote.

Provision's Proton Beam Application (February 2010)

In February 2010, Provision filed a CON application to initiate proton beam therapy services at the Dowell Springs Office Park. Proton beam therapy is a way of treating some types of cancer in certain patients. The service, which is not currently offered anywhere in Tennessee, is very costly and its clinical effectiveness compared to other modalities has been the subject of considerable debate. As required, Provision's application contained a detailed description of the proposed services to be offered and the equipment needed to provide those services. In its description of the proton project, Provision never claimed or suggested that an on-site linear accelerator would be needed to support the proton beam program. Covenant did not oppose the proton therapy project, but appeared at the hearing on the application in May 2010 to make known its concern that the proton project should not later be used as a justification for adding unneeded conventional radiation therapy in the area and to ensure that the proton project would be operated on open model, as set forth in the CON application. At the meeting where the proton beam application was considered, in response to questioning from an Agency member, Dr. Douglass assured the HSDA that a linear accelerator was **not** needed to support the proton project. Dr. Douglass' assertion at that time was confirmed by the testimony at the trial. Despite ETRTS' repeated efforts to attach the current application to the proton project, other safe and

successful proton centers do not operate on-site linear accelerators and the proton therapy center will go forward irrespective of what happens with the current application. The proton beam application was approved, to be operated under an open model, and that project is under construction.

Provision's Second CON Application (August 2011)

In August 2011, less than two years after its initial application for a conventional linear accelerator was denied by a 6 to 1 vote, Provision filed a second application again seeking approval to initiate conventional radiation therapy services at the Dowell Springs Office Park. Covenant Health, the University of Tennessee Medical Center, East Tennessee Children's Hospital, and Blount Memorial Medical Center all objected to Provision's application, which was heard at the December 2011 meeting of the HSDA. The Agency approved the Project by only a one-vote margin.

The Contested Case

Following the approval of the CON application, Covenant initiated a contested case, believing that the careful scrutiny of such a proceeding would expose that many of the claims made by Provision before the Agency were either misleading or just not accurate. After extensive pretrial discovery (including more than a dozen depositions and the exchange of thousands of documents), the contested case was heard beginning on January 14, 2013. In all, Judge Stovall heard testimony over two weeks from 15 witnesses, including two health care planning experts. All of the witnesses were subject to cross-examination and questioning by Judge Stovall. Approximately 200 exhibits were submitted for consideration. Both parties were given ample opportunity to present evidence and to argue their respective cases. Over the course of this proceeding, all of the rationales for ETRTS' project were exhaustively discussed.

Following completion of the trial, Judge Stovall spent an additional three months analyzing the evidence and the briefs and drafting a comprehensive and thorough 27-page Initial Order denying ETRTS' Certificate of Need.

ARGUMENT

I. **In concluding that the project was not needed, Judge Stovall examined *all* of the applicants' claims, and did not just rigidly apply the *Guidelines for Growth*.**

Faced with the Administrative Judge's rejection of all its arguments about need, ETRTS now pretends that the scope of the contested case was much narrower than it actually was and that only the quantitative guidelines were examined. Contrary to what ETRTS states in its Petition for Review, Judge Stovall did not simply "adher[e] strictly to the numerical benchmarks set out in the HSDA's *Guidelines for Growth*" in deciding that there was no need for the Project. (ETRTS Petition for Review, ¶10). Covenant never contended, and Judge Stovall did not find, that the *Guidelines for Growth* are dispositive on the issue of need. If that had been the approach, the trial could have been concluded very quickly, because throughout this process ETRTS has admitted its Project did not come close to meeting the need criteria in the *Guidelines for Growth*. Put simply, everyone agrees that, under the State Health Plan, there is no need for more linear accelerators in the Knoxville area.

The central issues addressed in the trial were not the numerical standards, but rather all of the other various explanations, rationalizations and justifications that have been advanced by ETRTS in support of its project. In fact, only one and one-half pages of the 26-page Initial Order addresses the *Guidelines for Growth* criteria. Most of the Order speaks to the other inadequate arguments advanced by ETRTS as to why the project should be approved. Judge Stovall's careful consideration exposed the applicant's arguments as being unsupported, misleading, speculative or just flat out wrong. For example:

- ETRTS claimed that population growth, especially growth in the elderly population, would lead to an increased need for linear accelerator capacity in the future. (Initial Order, ¶15). However, the proof showed that, even though the service area population has been increasing and aging for several years, the number of radiation treatments in the service area actually declined by 13%, from 72,900 in 2006 to 63,393 in 2011. (*Id.* at ¶16). This decline in demand is consistent with similar declines in other parts of the United States. (*Id.*) The number of radiation therapy treatments in the proposed service area has been declining for a variety of reasons, including advances in technology and reimbursement issues. (*Id.* at ¶17).
- ETRTS claimed that an onsite linear accelerator is necessary to treat so-called “concurrent therapy” patients – individuals who will require treatment from ETRTS’ approved but not yet operational proton therapy device and conventional photon therapy. (Initial Order, ¶20). ETRTS’ position now completely contradicts the position ETRTS previously took before the Agency, when it assured the HSDA that the proton therapy program would not require a linear accelerator to be located at the Dowell Springs Office Park. (*Id.* at ¶¶ 6-7).
- Moreover, with respect to ETRTS’ claims about “concurrent therapy patients,” even accepting their current claims at face value, the number of patients that might require treatment with both forms of radiation is quite small – at most 52 patients a year based on the proton therapy volume projections. The proof showed that these patients could successfully be treated by other existing radiation providers in the community. (Initial Order, ¶¶ 21-28).
- Whatever the number of sequential therapy patients, ETRTS has unequivocally stated that the Proton Therapy Center will move forward on schedule regardless of whether this CON is granted. (*Id.* at ¶28). The proof made it abundantly clear that the proton therapy program did not create a need for a new linear accelerator at Dowell Springs. (*Id.*)
- ETRTS also asserted that an onsite linear accelerator at Dowell Springs is necessary to complete the continuum of care at that location and to contribute to patient convenience. (Initial Order, ¶30). The “continuum of care” was a manufactured need that occurred because a group of physicians decided to move to an office park and offer medical oncology services. (*Id.*) Prior to this application, those physicians offered excellent care to their patients and elected to open an office at Dowell Springs knowing that a linear accelerator was not authorized for that location. (*Id.*)
- ETRTS’ final claimed justification for the project was that it is needed for research and development purposes. (Initial Order, ¶31). Although ETRTS suggested several potential research opportunities or possibilities, almost all of which involved the Proton Therapy Center and not conventional radiation therapy, the plans are all uncertain and speculative. (*Id.* at ¶34). There have been

no written proposals regarding the details of any arrangement between the Project and the University of Tennessee. (*Id.*) The proposed parties have not made any formal commitments to participate. (*Id.*)

Contrary to ETRTS' assertion, Judge Stovall methodically examined each and every justification offered by ETRTS in support of its contention that another linear accelerator is needed in the Knoxville service area. He fairly weighed the testimony of witnesses on both sides of the issue, measured the credibility of each, and ultimately decided that Covenant had carried its burden of proof by a preponderance of the evidence in demonstrating there was no need for ETRTS' project – either under the quantitative criteria of the *Guidelines for Growth* or under any other rationalization trumpeted by ETRTS. For ETRTS to now claim that Judge Stovall “adhered strictly to the numerical benchmarks” is false and is frankly disrespectful of the time, effort, and attention Judge Stovall devoted to this case. ETRTS put forward no credible rationale for why the guidelines in the State Health Plan should be ignored.

II. The proof showed that the proposed project would have a substantial negative impact on existing providers.

Based on some cherry-picked snippets from the Initial Order, ETRTS would also have the Agency believe that Judge Stovall decisively found that the project would not have a negative impact on existing providers. To the contrary, the Initial Order shows that the proof was basically undisputed that the project would have a \$1 million to \$1.5 million annual negative impact on Covenant alone, in addition to the substantial negative impact that it would have on other nonprofit providers, which providers objected to the CON application but did not participate in the contested case. Although Judge Stovall ultimately decided that, in his opinion, this detrimental financial impact did not quite warrant rejecting ETRTS' application, he also found that:

Although it could absorb the annual loss of \$1-\$1.5 million without jeopardizing its overall financial position, Covenant does raise a legitimate concern about the long term impact of the potential loss of revenue generating services that help subsidize services that lose money. Allowing niche providers to enter the marketplace and cherry pick profitable services could seriously impact the financial strength of those providers that offer a large variety of services that are essential to the community, many of which are costly to maintain and operate at a financial loss. This issue may however be one that is more appropriately addressed as matter of policy by the HSDA rather than in a decision relative to a specific CON contested case proceeding.

(Initial Order, Conclusions of Law, ¶8) (emphasis added).

III. **The Agency Should Not Re-Open this Matter.**

The contested case process exists so that certain applications can receive the kind of detailed examination that is simply impossible in the limited time available to the Agency. Through its Rules, the Agency created the process by which it refers contested cases to an ALJ for hearing on the Agency's behalf. *See* Agency Rule 0720-13.02(1). ETRTS cannot dispute that it had a full opportunity to present its case for the offering of new radiation therapy services before a fair and evenhanded ALJ, sitting for and on behalf of this Agency. Under these circumstances, there is no reason for the HSDA to review the case again.

Conclusion

For the foregoing reasons, Covenant requests that ETRTS' Petition for Review be denied.

Respectfully submitted,



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CERTIFICATE OF SERVICE

I hereby certify that a true and exact copy of the foregoing has been sent to the following counsel of record by the means indicated to the addresses below:

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This 3RD day of July, 2013.



16862945ButlerSnow

MEMORANDUM

TO: Health Services and Development Agency Members

FROM: Jim Christoffersen, General Counsel
Health Services and Development Agency

RE: East Tennessee Radiation Therapy Services LLC's
Request for HSDA Review of the Initial Order
Denying CON Application No. CN1108-030AD

DATE: July 16, 2014

Procedural History

1. By a 5-4 vote at its December 14, 2011 meeting, the HSDA approved East Tennessee Radiation Therapy Services LLC's ["ETRTS"] CON application, No. CN1108-030AD, for the establishment of an ambulatory surgical treatment center, acquisition of a linear accelerator and initiation of radiation therapy services at a specific location in the Dowell Springs area of Knoxville, Tennessee.
2. Covenant Health timely exercised its legal right to initiate a contested case to appeal the approval, pursuant to T.C.A. §68-11-1610.
3. The contested case (trial) was held over eight days in January 2013.
4. Sitting in place of the HSDA, Administrative Judge ["ALJ"] Tom Stovall issued the Initial Order on May 30, 2013, denying the CON application.
5. ETRTS timely petitioned the HSDA for review of the Initial Order. Copies of the petition, Covenant Health's reply, and ETRTS' response are attached.

The HSDA Must Decide *Whether* to Review the Initial Order

Agency Rule 0720—13—.03 provides as follows:

- (1) An Initial Order issued by an Administrative Judge, sitting alone, may be reviewed by The HSDA pursuant to T.C.A. §§4-5-301, et seq., 68-11-1610, these Rules, and the Rules of the Secretary of State Chapter 1360-4-1. The HSDA may, in its discretion, decline to exercise any review of an Initial Order issued by an Administrative Judge, in which event the Initial Order issued by an Administrative Judge shall become a Final Order as provided by the Administrative Procedures Act.

(2) In such a review proceeding, The HSDA's review is strictly limited to the record which was developed before the Administrative Judge. No additional evidence is to be received or considered by The HSDA.

(3) Such a review proceeding is in the nature of appellate review.¹ Each party will be given the opportunity to file a brief which should specify what action the party maintains The HSDA should take on the Initial Order. The HSDA may place reasonable page limitations on such briefs.

(4) In such a review proceeding, each party will normally be limited to oral argument of thirty (30) minutes in length, including rebuttal.

(5) At the conclusion of the review proceeding The HSDA may decide² that the Initial Order should be adopted in its entirety, or it may make such modifications to the Initial Order as it deems appropriate.³

The ALJ ruled that the action proposed in the application is not necessary to provide needed health care in the area to be served; ie., that “*Need*” was not established. Presumably, the parties would focus any HSDA review upon that criterion, and not economic feasibility or orderly development. Since everyone agrees that *Need* was not established under the quantitative criteria and standards of the state health plan, any HSDA review would need to focus upon whether good and sufficient reason otherwise exists to establish *Need* by a preponderance of the evidence.⁴ If the HSDA elects to undertake such a review, it must be mindful that the Chancery Court would require a reasonably sound basis being provided in the Final Order to support a decision made contrary to the criteria and standards of the state health plan. Whether such reason exists depends upon the specific facts of each case.

¹ The ALJ did not review the HSDA's decision, but heard this case *de novo*, which means that arguments and evidence for and against the application were submitted anew and within the procedural and evidentiary constraints of the Administrative Procedures Act. By law, HSDA review is about whether the ALJ made the right decision in denying the CON based upon the evidence established during the contested case, not whether the HSDA made the right decision after reviewing the application and hearing presentations on 12/14/11.

² The HSDA must openly consider findings of fact and conclusions of law for the Final Order before it is issued. This does not require a motion and vote for each finding individually, but at least discussion and consensus on each, followed by a vote for the Final Order. More discussion would be expected by a reviewing court for findings and conclusions that differ from the Initial Order.

³ The HSDA is not required to defer to the ALJ's findings of fact and conclusions of law when issuing a Final Order. However, in its review of the HSDA's Final Order in the Spring Hill Hospital contested case, the Davidson County Chancery Court made clear that findings of fact and conclusions of law reversed/replaced by the HSDA will be held to a higher level of scrutiny.

⁴ Generally, that over 50% of the evidence favors the finding.

**BEFORE THE TENNESSEE
HEALTH SERVICES AND DEVELOPMENT AGENCY
NASHVILLE, TENNESSEE**

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SECRETARY OF STATE

IN RE:

EAST TENNESSEE RADIATION
THERAPY SERVICES LLC
CN 1108-030A

)
) Docket No. 25.00-115208J
)
) CON No. CN 1108-030
)

**EAST TENNESSEE RADIATION THERAPY SERVICES LLC'S
REPLY IN SUPPORT OF PETITION FOR AGENCY REVIEW OF
ADMINISTRATIVE JUDGE'S ORDER DENYING A CON**

Contrary to what Petitioner Covenant Health ("Covenant") suggests in its Response to Respondent East Tennessee Radiation Therapy Services LLC's ("ETRTS") Petition for Agency Review, the Health Services & Development Agency ("HSDA") absolutely has the authority and ability to review the Initial Order issued on May 30th by the ALJ in this matter. That authority is conclusively provided in both the Uniform Administrative Procedures Act and the Health Services and Planning Act. *See* Tenn. Code Ann. §§ 4-5-315 and 68-11-1610(e). A review of the Initial Order by this Agency, therefore, is no more "extraordinary and unnecessary" than Covenant's own petition for contested case hearing, which set this proceeding in motion and is likewise authorized by § 68-11-1610(a).

Covenant would have the Agency deny the pending Petition for Review on the basis that it would be "difficult if not impossible" for HSDA to reach a considered decision based on all of the relevant evidence in this case. Response at 2. That position could not be farther from the truth. HSDA has the statutory authority to approve or deny CON applications, and it exercises that authority efficiently and effectively on a regular basis over the multitude of applications that come before it. This experience gives the HSDA a singular degree of expertise in balancing the

criteria relevant to CON applications that is unparalleled by any ALJ or court in the State. HSDA's "everyday administration" of its core functions and whether and how to enforce its rules are matters that fall "peculiarly within [an agency's] expertise." See *Wos v. E. M. A.*, 133 S. Ct. 1391, 1403 (2013) (Breyer, J., concurring); *Christopher v. Smithkline Beecham Corp.*, 132 S.Ct. 2156, 2168 (2012). Tennessee law recognizes "an agency's expertise and flexibility to deal with complex and changing conditions," *Bean v. McWhorter*, 953 S.W.2d 197, 199 (Tenn. 1997), and the Tennessee Supreme Court has consistently made clear "that administrative agencies have special expertise with regard to the subject matter of the proceedings before them." *B & B Enters. of Wilson County, LLC v. City of Leb.*, 318 S.W.3d 839, 847 (Tenn. 2010). Accordingly, just as was true in December 2011, the HSDA is perfectly capable of reviewing the record in this case and determining whether to grant a CON to ETRTS – and is, in fact, best situated to do so.

Indeed, in recent years, HSDA has exercised its authority to review an Initial Order on one or more occasions, including at least one case involving a project that was significantly larger and more complex than the ETRTS project, which involves only a single linear accelerator. See *In the Matter of Spring Hill Hosp., Inc.*, Docket No. 25.00-092967J. Importantly, the *Spring Hill Hospital* case involved a much larger record than the record in this case. In fact, in the *Spring Hill Hospital* case, the HSDA did not hesitate to review a record involving 49 witnesses, more than 150 exhibits and a nearly 2,000-page transcript. The record in this case is a fraction of that size.¹ The ability of this 11-member Agency to set a reasonable schedule that allows it to efficiently and effectively evaluate a set of facts that fall squarely within its collective expertise should not even be open to debate.

¹ In sharp contrast to the *Spring Hill Hospital* case, in this case, only 15 witnesses testified and only 80 exhibits were actually introduced into evidence.

Moreover, even if, as Covenant suggests, the HSDA's ability to review the Initial Order in this case were confined only to "unusual or extreme circumstances," this case presents just such a circumstance. Among other reasons, the HSDA should review this Initial Order because it directly contradicts the Agency's express and considered determination about the need for a linear accelerator on the Dowell Springs medical campus in Knoxville,² and, perhaps more importantly, because it calls into question HSDA's authority to conduct anything other than a robotic application of the numeric criteria set out in the *Guidelines for Growth* in future applications. As ETRTS's Petition for Review illustrates, and the Agency's review of the Initial Order will confirm, the lynch pin of the ALJ's Initial Order is that – despite the numerous benefits of the ETRTS project and its negligible impact on Covenant – the ETRTS CON must be denied because it "does not meet the objective criteria" set out in the *Guidelines*. See Initial Order at 16, 18, 21 and 23. This position is contrary to the law and to the Agency's own view of its authority, as expressed at its original hearing of this matter in December 2011.³ Covenant's claim that the ALJ did not consider those criteria to be outcome determinative is flatly contradicted by the ALJ's unapologetic, one-sentence denial of HSDA's own motion to reconsider the Initial Order, which was filed by the Agency's counsel and asked the ALJ to revise the Initial Order to make clear that an amendment to the State Health Plan or the HSDA rules

2. See HSDA Transcript dated Dec. 14, 2011 at 139-40 ("I'm also concerned about any additional radiation that would be required. If I were a patient there or my mother or my brother or my uncle, I would want the plan and the radiation delivered under the same planning and under the same system. As a consumer member, I think that's the right decision. . . .").

3. As HSDA Chairman Carl Koella stated at the December 2011 hearing: "[T]he need on a strictly mathematical basis is not the deciding factor. *Those are guidelines, they're not mandates.* We overlooked or found more important issues regarding the guidelines when we recently approved another linear accelerator for a hospital for the convenience of the hospital's patients. It wasn't needed then either and yet we did it. Sometimes it makes sense to do what we decide rather than based on strictly mathematical discussions." HSDA Transcript dated Dec. 14, 2011 at 138 (emphasis added).


was not necessary in order for the Agency to depart from the *Guidelines*. See ALJ Order dated June 25, 2013. It is, therefore, necessary for the Agency on review to set aside that purported limitation on its authority and to issue a ruling based upon its own evaluation of the many compelling factors in favor of granting the CON to ETRTS.

CONCLUSION

For the foregoing reasons, ETRTS respectfully requests that HSDA accept review of the ALJ's Initial Order, and that it issue a briefing schedule and set a date for substantive review of the Initial Order within a reasonable timeframe.

DATED this 11th day of July, 2013.

Respectfully submitted,



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I hereby certify that, on July 11, 2013, a true and correct copy of the foregoing was served via electronic mail and/or U.S. Mail upon the following:

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May 30, 2013

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RE: In the Matter of: East Tennessee Radiation Therapy Services
Docket No. 25.00-115208J

Enclosed is an Initial Order rendered in connection with the above-styled case.

Administrative Procedures Division
Tennessee Department of State

/aem
Enclosure

**BEFORE THE COMMISSIONER OF THE TENNESSEE
DEPARTMENT OF HEALTH**

IN THE MATTER OF:

**EAST TENNESSEE RADIATION
THERAPY SERVICES**

DOCKET NO. 25.00-115208J

NOTICE

ATTACHED IS AN INITIAL ORDER RENDERED BY AN ADMINISTRATIVE JUDGE WITH THE ADMINISTRATIVE PROCEDURES DIVISION.

THE INITIAL ORDER IS NOT A FINAL ORDER BUT SHALL BECOME A FINAL ORDER UNLESS:

1. THE ENROLLEE FILES A WRITTEN APPEAL, OR EITHER PARTY FILES A PETITION FOR RECONSIDERATION WITH THE ADMINISTRATIVE PROCEDURES DIVISION NO LATER THAN **June 14, 2013**.

YOU MUST FILE THE APPEAL, PETITION FOR RECONSIDERATION WITH THE ADMINISTRATIVE PROCEDURES DIVISION. THE ADDRESS OF THE ADMINISTRATIVE PROCEDURES DIVISION IS:

SECRETARY OF STATE
ADMINISTRATIVE PROCEDURES DIVISION
WILLIAM R. SNODGRASS TOWER
312 ROSA PARKS AVENUE, 8th FLOOR
NASHVILLE, TENNESSEE 37243-1102

IF YOU HAVE ANY FURTHER QUESTIONS, PLEASE CALL THE ADMINISTRATIVE PROCEDURES DIVISION, **615/741-7008 OR 741-5042, FAX 615/741-4472**. PLEASE CONSULT APPENDIX A AFFIXED TO THE INITIAL ORDER FOR NOTICE OF APPEAL PROCEDURES.

**BEFORE THE TENNESSEE HEALTH SERVICES
AND DEVELOPMENT AGENCY**

IN THE MATTER OF:

**EAST TENNESSEE RADIATION
THERAPY SERVICES, LLC**

CON No. CN 1108-030

DOCKET NO. 25.00-115208J

INITIAL ORDER

This matter came to be heard on January 14-18, 24-25 and 29, 2013, before Thomas G. Stovall, Administrative Judge, sitting for the Tennessee Health Services and Development Agency (HSDA) in Nashville, Tennessee. The Petitioner, Covenant Health (Covenant), was represented by counsel, Mr. G. Brian Jackson and Mr. Travis B. Swearingen, of Nashville. The Applicant, East Tennessee Radiation Therapy Services, LLC (ETRTS), was represented by counsel, Mr. W. Brantley Phillips, Jr. and Mr. Russell S. Baldwin, of Nashville. The HSDA was represented by Mr. James B. Christoffersen, General Counsel.

The subject of this hearing is the appeal filed by Covenant of the granting of a certificate of need (CON) to ETRTS by the HSDA to establish an ambulatory surgical treatment center for the installation of a linear accelerator (LINAC) to provide radiation therapy in Knoxville, Tennessee. After consideration of the record in this matter, it is determined that the CON application of ETRTS should be **DENIED**. This decision is based upon the following findings of fact and conclusions of law.

FINDINGS OF FACT

The Parties

ETRTS

1. ETRTS is a non-profit subsidiary of Provision Healthcare (Provision) located at the Dowell Springs medical office park in Knoxville, Tennessee. ETRTS was formed for the purpose of providing conventional radiation therapy services using a single LINAC at Dowell Springs.

2. Provision was conceived by Terry Douglass, Ph.D. Dr. Douglass is an entrepreneur who has had a successful career in developing and marketing medical technology to hospitals and other health care providers. Over the last decade, Provision has acquired land in the Dowell Springs area with a vision of developing a comprehensive cancer outpatient, diagnostic, research and treatment center at the location.

Covenant Health

3. Covenant is a non-profit corporation with its principal offices in Knoxville. Covenant is the parent corporation for a system that operates hospitals, cancer centers, and other health care facilities. Covenant also engages in many other health care related activities. Covenant owns and operates the largest health care system in East Tennessee. Covenant owns seven acute care hospitals with over 1,500 licensed beds. These seven hospitals include three large tertiary facilities, Fort Sanders Regional Medical Center and Parkwest Medical Center in Knoxville, and Methodist Medical Center of Oak Ridge, as well as four smaller community hospitals in Sevierville, Lenoir City, Harriman and Morristown. Covenant also owns the Thompson Cancer Survival Centers (Thompson), which consist of 10 locations across East Tennessee. Five of those sites, Morristown, Sevierville, Knoxville Downtown (Ft. Sanders),

Knoxville West (Parkwest), and Oak Ridge, are “comprehensive cancer services” in that they provide a full spectrum of oncology services. Thompson operates a total of eight LINACS at these cancer treatment centers.

HSDA

4. The HSDA was created by the Tennessee Health Services And Planning Act Of 2002, Tenn. Code Ann. Title 68, Chapter 11, Part 16. The HSDA is tasked with administering the CON program in Tennessee.

Procedural History

5. In 2008-2009, Provision constructed a building within the Dowell Springs Office Park for the specific purpose of housing two LINACs. In July 2009, Provision filed an application with the HSDA for a CON seeking approval to purchase a LINAC to initiate radiation therapy services at Dowell Springs. In December 2009, the HSDA denied the CON application, citing the lack of demonstrated need for an additional LINAC in the service area.

6. In February 2010, Provision filed a CON application to initiate proton beam therapy services at Dowell Springs. Proton beam therapy is a unique form of radiation therapy that uses a controlled beam of protons to target tumors with control and precision unavailable in other radiation therapies. Proton therapy has the ability to more precisely localize the radiation dosage, which limits damage to healthy surrounding tissue and results in minimal or no side effects to the patient. Currently there are less than a dozen proton beam therapy facilities in the United States, with the closest to Knoxville being about 350 miles away.

7. In its description of the project, Provision never claimed or suggested that a LINAC would be needed to support the proton beam program. While Covenant did not oppose the CON application for the proton beam center, when the HSDA met on May 26, 2010, to

review Provision's application, Covenant did raise the concern as to whether the proton beam project if approved would later be used as a justification for a LINAC. A Covenant representative made the following statement to the HSDA:

The first concern is how this application relates to linear accelerator service. And specifically, Covenant would like to be sure that the proton beam service would not be used as a premise later on to add a linear accelerator that otherwise is not justified in the CON criteria or perhaps even to add a linear accelerator even before the proton beam service is operational. We suggest this concern is understandable because as the agency will recall, an affiliate of the applicant at this same site applied for and was denied a linear accelerator only five months ago.

In response, Provision representatives confirmed that they did not intend to seek conventional radiation therapy services as part of the proton beam project and that an on-site LINAC was not needed for proton therapy. Specifically, Dr. Douglass had the following exchange with an HSDA board member:

MR. GAITHER: To have an appropriate proton therapy model do you need a linear accelerator?

DR. DOUGLASS: No, you do not. In fact, you may in the future combine proton therapy and linear accelerators but we have other linear accelerators in the community.

8. The HSDA approved Provision's CON application for a proton beam therapy center. Provision intends to have the proton beam center operational by 2014.

9. On August 15, 2011, Provision (ETRTS) filed a CON application to initiate conventional radiation therapy services with a LINAC at the Dowell Springs Office Park. The CON was approved by the HSDA on December 14, 2011. ETRTS implemented the CON and the LINAC has been operational at Dowell Springs since August 2012. By the time of the hearing ETRTS had delivered approximately 1,000 radiation treatments to 40 patients.

10. Covenant filed an appeal of the HSDA decision to approve the CON for the ETRTS linear accelerator which is the subject of this proceeding.

CON General Criteria and Guidelines For Growth

11. Tenn. Code Ann. §68-11-1609(b) provides:

No certificate of need shall be granted unless the action proposed in the application is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, and will contribute to the orderly development of adequate and effective health care facilities or services. In making such determinations, the agency shall use as guidelines the goals, objectives, criteria and standards in the state health plan.

Need

12. For the purposes of a CON application, the service area is the geographic location from which the applicant believes most of its patients will originate. The ETRTS application asserts that the project's service area is the 16-county area surrounding and including Knox County. Using a 16-county service area allows ETRTS to capture the population of those counties when calculating the State Health Plan's population-based need criteria. The population of the service area was approximately 1.2 million in 2012.

13. The State Health Plan provides that each radiation therapy unit should serve a population base of at least 120,000 people. Excluding the ETRTS project, presently there are 17 approved LINACs (15 currently operational) in the service area. Despite the guidelines set forth in the State Health Plan, currently there is one operational linear accelerator for every 80,000 people in the service area, or approximately 67% of the State Health Plan target. When the ETRTS LINAC is added to the mix, there is one operational linear accelerator for every 75,000 people in the service area, or approximately 63% of the State Health Plan target. If the remaining two unimplemented but approved linear accelerators become operational, there will be

one approved linear accelerator (including the ETRTS project) for every 67,000 persons in the service area, or approximately 56% of the State Health Plan target.

14. The State Health Plan also establishes a minimum annual capacity of 6,000 procedures per unit. Based on the most recent HSDA data, the average utilization of the operational linear accelerators in the service area was approximately 5,000 procedures per unit in 2011, or just 84.2% of the minimum standard.

15. Deborah Kolb Collier, Ph. D., is a health planning expert who testified on behalf of Covenant in this case. Based upon the population and utilization figures set forth above, it is the opinion of Dr. Collier that the ETRTS project does not meet the criteria set forth by the State Health Plan and the Guidelines for Growth to establish a need for an additional LINAC in the service area. Both the HSDA and ETRTS concede this fact. Daniel Sullivan, who testified as a health planning expert on behalf of ETRTS, testified as follows:

Q. ...you would agree that – looked at – according to the criteria and everything, there's not a need for a new linear accelerator in Knoxville...right?

A. (Sullivan) From a quantitative standpoint, I would agree with that.

Q. And one of the Guidelines for Growth criteria that applies in this case is that every linear accelerator should serve a population of at least 120,000, right?

A. Yes.

Q. And I understand you have issue – you don't really like that guideline very much, right?

A. I don't.

Q. But you agree that the project as proposed doesn't satisfy it, correct?

A. I would agree with that.

15. Despite the fact that ETRTS concedes that the project does not meet the objective criteria to establish a need for an additional LINAC in the service area, it contends that Dr. Collier's analysis is flawed because she failed to adequately account for other factors specific to the service area that will cause increased utilization rates in the future and ensure a need for a new LINAC. These factors are population growth, an aging population and a high cancer rate. It was agreed by all the experts that a modest growth in population is to be expected in the service area. According to the Tennessee State Data Center, the service area population will grow by about 48,000 or 4.1% between 2010 and 2015. The service area population has been aging for several years and therefore the percentage of the population most susceptible to cancer is increasing. The fastest growing segment of the population is expected to be the age group of 65-74 years old, which is anticipated to increase by 24% between 2010 and 2015. This is most significant because the service area already has a higher rate of cancer than other parts of Tennessee. Between 2005 and 2009, 14 of the 16 counties in the service area experienced a higher rate of cancer than the statewide average.

16. According to Dr. Collier, she did consider these demographic changes when coming to the conclusion that the ETRTS project does not meet the need criteria. Dr. Collier noted that despite these demographic trends, between 2006 and 2011 the total number of radiation fractions in the proposed service area declined by 13%, from 72,891 to 63,393. This decline in demand is consistent with similar declines in other parts of the United States.

17. Dr. Collier believes there are numerous factors at work in the market that may be resulting in the reduction in demand for traditional radiation therapy services. Perhaps the most significant are changes and advances in technology that provide other ways for patients to receive care for treatment of cancer, such as High-Dose Rate Brachytherapy, GammaKnife and

CyberKnife technologies. It is Dr. Collier's opinion that despite the population growth and demographic changes that might suggest an increased number of radiation therapy treatments to be performed in the service area in the future, they will be offset by other factors that have resulted in a decrease in the utilization rate over the last few years.

18. Mr. Sullivan, testifying on behalf of ETRTS, believes the demographic data specific to the service area (population growth, aging of the population and high cancer rate) will result in an increase in demand for radiation treatment despite the recent decline in such usage. However, Mr. Sullivan conceded that earlier such projections would have been incorrect when he testified as follows:

Q. Sure. But if you had been – for example, if you had been hired by Provision back in 2009, you knew they filed an application for a CON back then, right?

A. (Sullivan) They did.

Q. And if you had come in and told the Court or the Agency then, well, you think that radiation – demand for radiation therapy services is going to go up in the future, you would have been wrong, right?

A. I would have been.

Q. And, in fact, since that application was filed in 2009, we've seen two years of declining utilization, right?

A. We have.

19. Despite the fact that all parties agree that an additional LINAC is not supported by the objective criteria set forth in the State Health Plan, ETRTS contends there are a number of other factors which justify approval of the CON application.

20. ETRTS argues that an onsite linear accelerator is necessary to treat so-called "concurrent therapy" patients – individuals who will require both proton beam therapy and conventional photon therapy. This is in spite of Dr. Douglass's statement to the contrary to the

HSDA in 2010 when asked whether an appropriate proton beam therapy model required an on-site linear accelerator. (Finding of Fact No. 7)

21. In support of this contention, ETRTS offered as an expert witness Carl J. Rossi, M.D. Dr. Rossi is a radiation oncologist with over 20 years of experience in performing proton beam therapy on cancer patients. Most of Dr. Rossi's career was at Loma Linda University Medical Center in Loma Linda, California. Since 2011, Dr. Rossi has been the medical director of the Scripps Proton Therapy Center in San Diego, California. Dr. Rossi testified that he believed there was a need for an onsite linear accelerator at Dowell Springs to supplement and support the proton beam therapy center, both to provide sequential therapy to patients when necessary and in the event that the proton machine broke down.

22. Dr. Rossi estimated that 10-20% of proton beam therapy patients require combination therapy using the proton beam and conventional radiation therapy with a linear accelerator. Some combination therapy treatments are provided concurrently, meaning that the patient receives proton therapy and conventional radiation therapy on the same day. Other combination therapy treatments are provided sequentially, meaning that the patient receives an entire course of proton therapy followed by a course of conventional radiation therapy. It is undisputed that combining proton beam treatment and conventional radiation therapy is complex and that this added complexity can lead to an increased risk of error in administration of the treatment. As a result, an extraordinary level of coordination is required in order to optimize the safety and treatment outcomes for combination therapy patients. Dr. Rossi believes that in an optimal setting combination therapy should be delivered in a totally integrated facility where you have the same treatment team performing all functions and utilizing the same modalities and computer software.

23. It appears however that the integration of the treatment facilities has very little to do with the physical location of the proton beam center and the linear accelerator. At the Scripps Center where Dr. Rossi works, the proton beam center and the LINAC are three to four miles apart. One program discussed at length is the Indiana Health Proton Therapy Center associated with Indiana University Medical Center. Although part of the same network, the proton beam center is located in Bloomington, Indiana, with the LINAC located in Indianapolis over 50 miles away and owned by a separate entity. ProCure is also a company that operates proton beam therapy centers in Illinois, New Jersey, Oklahoma and Washington state. Two of these ProCure proton therapy centers have partners that ProCure does not own but that provide conventional radiation therapy with a LINAC to patients who are also receiving proton beam therapy at a ProCure center. ProCure uses a composite planning system to safely and effectively combine treatment plans with its outside partners, despite the fact that ProCure and its partners use different treatment planning systems.

24. While perhaps optimal, it clearly is not necessary for the proton beam center and a linear accelerator to be located on the same campus or even in the same city to provide appropriate combination therapy to cancer patients. Nor does it appear essential that the two treatment centers be owned by the same entity or use an identical treatment planning system.

25. Both the proton beam center and the ETRTS facility are organized for "open model" staffing, which allows for any properly qualified physician to utilize the equipment regardless of the physician's affiliation with another provider. Covenant has committed to having its physicians fully trained and qualified in order that they will be able to treat patients at the proton beam facility.

26. Chester R. Ramsey, Ph.D., is the Chief Medical Physicist for the Thompson Centers, which are owned by Covenant. As previously stated, Thompson operates 10 locations in the service area. Dr. Ramsey is an adjunct professor at the University of Tennessee's (UT) School of Engineering and has taught medical physics courses at UT since 1997. For the past 15 years, Thompson has been training medical physics residents on the most advanced treatment techniques with its physics residency program offered through UT. Although Dr. Ramsey is not a physician and has never personally administered proton beam therapy, he has extensive knowledge of the therapy and has done considerable research on the topic. Dr. Ramsey wrote his master's thesis on proton therapy, authored several papers on proton therapy and has reviewed hundreds of peer-reviewed scientific manuscripts on the topic. Dr. Ramsey has extensively prepared for the opportunity to participate in the open and collaborative model proposed for the proton beam center. In Dr. Ramsey's opinion, through careful planning and collaborative effort, sequential patients can be safely treated at an off-site linear accelerator operated by Thompson or one of the other local providers in the service area. Dr. Ramsey addressed the four criteria suggested by Dr. Rossi as critical to the appropriate coordination between a proton beam center and a LINAC: 1) the treatment team at the LINAC center must all be appropriately trained and credentialed on the use of the proton therapy machine; 2) the LINAC provider must use the same proton treatment planning system as the proton therapy center; 3) the LINAC provider must use the same immobilization devices as the proton beam center; and 4) the LINAC provider must use the same electronic medical records system. Dr. Ramsey believes that all these criteria can be safely accomplished through the use of existing radiation therapy providers in the service area. As stated above, Covenant has already committed to having its physicians and technicians fully trained and qualified in order to obtain the certifications necessary to become credentialed at the

proton beam center. Covenant has committed to purchasing the same planning system used at the proton beam center. Covenant already uses the same immobilization devices and the same electronic medical record system proposed to be used at the proton beam center. In other words, Covenant has either already taken or has agreed to take whatever steps are necessary to safely implement the open and collaborative proton therapy model contemplated by Provision in the development of the proton beam center. Finally, it should be noted that two of the Thompson Centers, Thompson West and Thompson Downtown, are each located approximately seven miles from the Dowell Springs campus where the proton beam center will be located. These two locations are in close enough proximity to the proton beam center to allow for easy coordinated treatment plans.

27. Although Covenant is confident that it and other area providers could meet the demand for LINAC services generated by patients requiring combination proton therapy and traditional radiation therapy, there is considerable debate as to exactly what percentage of proton beam patients would need combination therapy. The evidence suggests that Dr. Rossi's estimate of 10-20% of the patients needing combination therapy is too high. Dr. Rossi himself testified that his estimate was based solely on his memory and he had not looked at any data upon which he based his estimate. After this CON application for a LINAC was filed by ETRTS in August 2011, Scott Warwick, Vice President of Clinical Operations for Provision, began to communicate with representatives of other proton beam centers in an effort to determine whether the 10-20% estimate was accurate based upon the experience at other centers. Evidence presented from other facilities suggests that the typical percentage is actually lower – ranging from zero percent (0%) at M.D. Anderson to five percent (5%) at the Indiana Health Proton Therapy and the two ProCure proton therapy facilities and ten percent (10%) at Hampton

University. Provision has estimated that it will treat 670 patients annually at the proton beam center by the second year of operation. If one assumes that 5-10% of patients needing combination therapy is a more reasonable estimate than Dr. Rossi's 10-20% estimate, one can assume that less than 65 patients per year treated at the ETRTS proton beam center would require combination therapy. It is reasonable to assume that Covenant's Thompson Centers, as well as the other providers in the service area, would be able to absorb this relatively small number of new patients at their LINAC centers, especially in light of the underutilization of the existing linear accelerators. (Finding of Fact No. 14)

28. The success of the proton beam center is not dependent on whether a LINAC is approved for the Dowell Springs campus. Dr. Douglass himself said as much when testifying before the HSDA in May 2010, when the agency was considering the CON application for the proton beam center. (Finding of Fact No. 7) Dr. Rossi also agreed that a proton therapy facility can operate safely and effectively without an on-site linear accelerator.

29. Another reason offered by ETRTS in support of the need for a LINAC at Dowell Springs was the continuum of care and convenience it would provide patients receiving treatment from the two physician groups located there. Knoxville Comprehensive Breast Center (KCBC) and Tennessee Cancer Specialists (TCS) re-located their offices to Dowell Springs in 2008 and 2009 respectively. It must be noted that at the time of the re-location of these two physician groups there was no LINAC at Dowell Springs.

30. ETRTS offered the testimony of Dr. Russell DeVore, an oncologist and a partner in TCS, regarding "continuum of care" and "patient convenience" issues. Dr. DeVore testified that TCS re-located from locations that already had an onsite linear accelerator because of Dowell Springs' more central location in Knox County where most of their patients came from.

In fact, Tennessee Cancer Specialists chose to open the office in Dowell Springs even though there were multiple comprehensive cancer centers in the area which already had linear accelerator services and where, in many instances, TCS already had offices. Every other TCS office except for Dowell Springs is located on or near a hospital campus. It would appear that the need for a linear accelerator at the same location where the TCS office was located to enhance the opportunity for a continuum of care was not an overriding concern for the group when it re-located its offices to Dowell Springs in 2009. Dr. Devore admitted that he never had difficulty finding suitable treatment for his patients at existing LINACS prior to the installation of the ETRTS linear accelerator pursuant to this CON.

31. As an additional factor in demonstrating the need for a LINAC at Dowell Springs, ETRTS emphasized the potential for research and educational opportunities that will exist at the medical complex. An important aspect of the Provision complex at Dowell Springs is the Center for Biomedical Research (CBR). Currently, clinical trials are being conducted on patients receiving cancer treatment from the providers at Dowell Springs. It is the goal of Dr. Douglass to significantly enhance the research capabilities at Dowell Springs. He believes that having access to both a linear accelerator and a proton beam on site will increase clinical trial capabilities and lead to a greater level of research. Dr. Douglass stated that he hopes to use the traditional radiation center and the proton therapy center to help develop the "next generation proton therapy equipment."

32. Alan G. Meek, M.D., has been the medical director at ETRTS since August 2012. Prior to coming to ETRTS, Dr. Meek had been the chairman of the Radiation Oncology Department at the State University of New York at Stony Brook Health Sciences Center. Dr. Meek intends to conduct a variety of research using the ETRTS linear accelerator, including

collaborating with the medical oncologists on clinical trials, continuing his own research on the best position in which to deliver radiation to breast cancer patients and experimenting with radiopharmaceuticals created in the on-site cyclotron to improve the diagnostic imaging used for cancer treatment planning. Dr. Meek also is collaborating with UT on the development of a radiation oncology department, which the UT School of Medicine currently lacks. Dr. Meek is in the process of receiving a faculty appointment with the UT Department of Biomedical Engineering as well as a clinical appointment with the School of Medicine.

33. Provision is also actively pursuing collaborative research efforts with the Oak Ridge National Laboratory (ORNL) and UT. David Millhorn, Ph. D., is the Executive Vice President and Vice President for Research and Economic Development for UT. According to Dr. Millhorn, one of the many projects UT is discussing with Provision and ORNL is the development of a new Joint Institute for Radiologic Sciences and Imaging which would use the Dowell Springs campus as an education, training and research site. UT currently does not have an accredited medical physics program, and it is in the process of establishing such a program. Dr. Millhorn testified that UT is discussing with Provision a collaborative partnership on this project.

34. Most if not all of the research projects outlined by Dr. Millhorn that would involve UT have not progressed beyond the discussion and planning stages. No written plans have been submitted and no contracts have been signed. The proposed parties have not made any formal commitments to participate. Moreover, ETRTS could have sought a CON for research purposes only if it believed that a linear accelerator was necessary to pursue joint research and development efforts with UT and ORNL.

35. Clinical research is currently taking place in the Knoxville marketplace. UT and Thompson have been collaborating on medical physics education for the last ten years.

Economic Feasibility

36. It is uncontested by the parties that this project can be economically established and maintained. ETRTS immediately implemented the CON and it began operation in August 2012. ETRTS had treated approximately 40 patients by the time of the hearing in January 2013. It is without question that Provision has the financial resources to appropriately maintain a LINAC at Dowell Springs.

Orderly Development of Healthcare

37. There are many aspects to an analysis of whether a project proposed in a CON application will contribute to the orderly development of healthcare in a given market. The need for the ETRTS linear accelerator has previously been discussed at length, as has the possibility of collaborative research and educational projects with UT and ORNL. A significant factor that has yet to be addressed in this analysis is the potential impact of this proposal on other providers in the service area.

38. At the present time the primary providers of traditional radiation therapy in the service area are Covenant, Blount Memorial Hospital in Maryville, Tennova and UT Medical Center.¹ In 2011, Covenant had 53.7% of the market share for radiation therapy treatments, more than three times the market share of its nearest competitor, Tennova with 16.7%

39. Covenant's expert Dr. Collier estimated that Covenant would experience a loss of radiation therapy patients to ETRTS that would result in a financial loss of approximately \$1.5 million annually. As set forth in Finding of Fact No. 15, ETRTS disagreed with Dr. Collier's utilization projections as her projections did not adequately take into account factors such as

¹ Only Covenant objected to the CON before the HSDA.

population growth, an aging population and a high cancer rate. When those factors are considered in an analysis of future utilization rates and the potential financial impact on Covenant of the LINAC at Dowell Springs, ETRTS's expert Daniel Sullivan estimated that Covenant would only lose \$1 million annually.

40. Available cash flow, or a company's revenue after expenses, is a key financial metric for any organization. In the accounting industry "cash flow" is commonly represented by the term EBITDA – Earnings Before Interest, Taxes, Depreciation and Amortization. Hospitals tend to record substantial amounts of depreciation due to their large investments in fixed assets. In reality, however, depreciation and amortization are not actual cash expenses and do not reduce the cash available to the hospital for the purpose of paying bills, salaries and expenses, making capital expenditures or servicing its debt. Accordingly, the primary focus in evaluating the financial strength of an organization is on its EBITDA cash flow and financial position. This is confirmed by the fact that EBITDA/cash flow accounts for ten of the 27 metrics used by Fitch, Inc. in rating the creditworthiness of non-profit hospital bonds.

41. In the case of Covenant, its EBITDA cash flow from operations is substantial and consistently positive. In fact, Covenant's EBITDA cash flow has increased every year since 2008. Specifically, during the four years 2008 to 2011, Covenant's annual EBITDA was approximately \$71.1 million, \$84.4 million, \$90.5 million and \$91.6 million, respectively.

42. Covenant's annual EBITDA for the years 2009 to 2011 increases to \$120 million, \$112 million and \$135 million, respectively, if income from investments and other activities is added to its EBITDA cash flow from operations.

43. Because of its substantial annual EBITDA cash flow, since 1999 Covenant has averaged annual increases of more than \$48 million in its cash and investment reserves. Due to

its substantial annual EBITDA cash flow, as of December 31, 2011, Covenant had more than \$1.034 billion in cash and investments. Covenant reported that as of September 30, 2012, it had nearly \$1.05 billion in cash and investment reserves.

44. Due to Covenant's overall financial strength, an annual loss in revenue of \$1-\$1.5 million as a result of patients going to ETRTS for treatment instead of Covenant facilities should not have a significant negative impact on the company's viability.

45. However, it is a legitimate concern on the part of Covenant that the potential loss of revenue in profitable service areas could impact its ability to provide services that are not profitable. For example, Covenant operates Peninsula Hospital which offers inpatient psychiatric treatment. Peninsula is the largest psychiatric hospital in Tennessee, and the only provider of inpatient psychiatric in the service area since the State of Tennessee closed Lakeshore Mental Health Institute in 2012. Peninsula now contracts with the Tennessee Department of Mental Health and Substance Abuse Services to accept patients who previously would have been admitted at Lakeshore.

46. Anthony L. Spezia is the President and CEO of Covenant. Mr. Spezia stated that despite the fact that Covenant loses approximately \$3-4 million a year providing inpatient behavioral health services at Peninsula, Covenant intends to continue providing those services because it is essential to the community. In contrast to inpatient psychiatric services, radiation therapy such as being offered by ETRTS is typically a service that is a positive revenue generator. Mr. Spezia stated that non-profit community hospitals and health systems like Covenant must rely on profitable services like radiation therapy to subsidize many important medical services like psychiatric care that may not generate positive revenue.

47. Thus, while it has clearly not been established that the entry of ETRTS into the market will have a crippling financial impact on Covenant, as Mr. Spezia outlined it is a delicate balance that must be maintained if healthcare organizations are going to be able continue to provide all types of services that modern society expects, including those that are not profitable such as psychiatric care.

CONCLUSIONS OF LAW

1. In a contested case hearing before the Agency, the party petitioning for the hearing bears the burden of proof to establish by a preponderance of the evidence, that the CON should be granted or denied. Tenn. Comp. R. & Regs. Rule No. 0720-13-.01(3) In this case, Covenant has the burden of proof to establish that the CON granted to ETRTS should be denied. It is determined that Covenant has carried this burden of proof.

2. Tenn. Code Ann. §68-11-1609(b) provides:

No certificate of need shall be granted unless the action proposed in the application is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, and will contribute to the orderly development of adequate and effective health care facilities and/or services. In making such determinations, the agency shall use as guidelines the goals, objectives, criteria and standards in the state health plan. Until the state health plan is approved and adopted, the agency shall use as guidelines the current criteria and standards adopted by the state health planning and advisory board, and any changes implemented thereto by the state health planning division pursuant to §68-11-1625. Additional criteria for review of applications shall also be prescribed by rules of the agency.

3. Rule 0720-11-.01 sets forth the additional criteria for review of CON applications as adopted by the Agency:

GENERAL CRITERIA FOR CERTIFICATE OF NEED. The Agency will consider the following general criteria in determining whether an application for a certificate of need should be granted:

(1) Need. The health care needed in the area to be served may be evaluated upon the following factors:

- (a) The relationship of the proposal to any existing applicable plans;
- (b) The population served by the proposal;
- (c) The existing or certified services or institutions in the area;
- (d) The reasonableness of the service area;
- (e) The special needs of the service area population, including the accessibility to consumers, particularly women, racial and ethnic minorities, TennCare participants, and low-income groups;
- (f) Comparison of utilization/occupancy trends and services offered by other area providers;
- (g) The extent to which Medicare, Medicaid, TennCare, medically indigent, charity care patients and low income patients will be served by the project. In determining whether this criteria is met, the Agency shall consider how the applicant has assessed that providers of services which will operate in conjunction with the project will also meet these needs.

(2) Economic Factors. The probability that the proposal can be economically accomplished and maintained may be evaluated upon the following factors:

- (a) Whether adequate funds are available to the applicant to complete the project;
- (b) The reasonableness of the proposed project costs;
- (c) Anticipated revenue from the proposed project and the impact on existing patient charges;
- (d) Participation in state/federal revenue programs;
- (e) Alternatives considered; and
- (f) The availability of less costly or more effective alternative methods of providing the benefits intended by the proposal.

(3) Contribution to the Orderly Development of Adequate and Effective Healthcare Facilities and/or Services. The contribution which the proposed project will make to the orderly development of an adequate and effective health care system may be evaluated upon the following factors:

(a) The relationship of the proposal to the existing health care system (for example: transfer agreements, contractual agreements for health services, the applicant's proposed TennCare participation, affiliation of the project with health professional schools);

(b) The positive or negative effects attributed to duplication or competition;

(c) The availability and accessibility of human resources required by the proposal, including consumers and related providers;

(d) The quality of the proposed project in relation to applicable governmental or professional standards.

4. As is often the situation when reviewing the merits of a CON application and applying the criteria set forth in the law to that application, an analysis of the ETRTS project does not lend itself to the neat categorization of need, economic feasibility and orderly development of healthcare. These factors are usually inter-related, and that certainly is the case in the instant appeal. The following analysis will, however, attempt to address each criterion individually.

5. It must be stated at the outset that it would appear that what has been created by Provision at the Dowell Springs campus, and what Dr. Douglass hopes to develop in the future, is a state of the art, all encompassing cancer treatment and research center that will benefit not only the Knoxville area but the entire southeastern United States. Dr. Douglass and his partners are to be commended in having the foresight and resources to create this medical complex. The physician groups that have re-located to Dowell Springs over the last few years and the proton

beam center scheduled to begin operation in 2014 will provide excellent cancer treatment for patients. The collaborative research and educational projects being discussed with both ORNL and UT are to be encouraged and may hopefully result in advancements in cancer treatment and medical education. Despite these laudatory goals and achievements, the analysis in this case must be focused on the criteria for approval of a CON as set forth by law. Most if not all of the activities currently taking place at Dowell Springs as well as those in the planning stage can proceed without a LINAC on site, either because a LINAC is not needed or by the use of an existing LINAC owned by a neighboring provider when necessary. The entire case comes down to the simple fact that there is a lack of demonstrated need for another linear accelerator in the service area, and all of the present and future accomplishments at Dowell Springs cannot mask that fact. An applicant cannot “create the need” for a project by developing other services and recruiting physicians when that need does not otherwise exist.

Economic Feasibility

6. As set forth in Finding of Fact No. 36, it is uncontested by the parties that this project can be economically established and maintained.

Orderly Development of Healthcare

7. The proof in this case did not establish that the ETRTS linear accelerator would negatively impact the orderly development of healthcare in the service area. In Findings of Facts Nos. 39-44, it was established that due to the financial strength of Covenant, an annual loss of \$1-\$1.5 million in revenue would not seriously damage Covenant’s long-term financial viability. Covenant’s annual EBITDA, including income from investments and other activities, for the year 2011 was \$135 million. Covenant reported that in 2012 it had over \$1 billion in cash and investment reserves. It stands to reason that a company with the financial reserves of Covenant

could withstand an annual loss of \$1-\$1.5 million without experiencing significant financial hardship.

8. Although it could absorb the annual loss of \$1-\$1.5 million without jeopardizing its overall financial position, Covenant does raise a legitimate concern about the long term impact of the potential loss of revenue generating services that help subsidize services that lose money. (Findings of Fact Nos. 45-47) Allowing niche providers to enter the marketplace and cherry pick profitable services could seriously impact the financial strength of those providers that offer a large variety of services that are essential to the community, many of which are costly to maintain and operate at a financial loss. This issue may however be one that is more appropriately addressed as matter of policy by the HSDA rather than in a decision relative to a specific CON contested case proceeding.

9. Another aspect of the orderly development of healthcare is the “affiliation of the project with health professional schools” and other entities in the area. The collaborative research and educational pursuits being discussed with UT and ORNL certainly would contribute to the orderly development of healthcare in the area. However, as noted previously, most of these proposals are still in the discussion stage and do not require an on-site LINAC to be viable.

Need

10. As stated above, this case turns on whether there is a need for a new linear accelerator in the Knoxville service area. It is concluded that such a need does not exist. As discussed extensively in Findings of Fact Nos. 12-18, this project does not meet the objective criteria set forth in the State Health Plan to justify the addition of a new LINAC in the market.

All parties are in agreement on this fact.² Indeed, Daniel Sullivan, an expert working on behalf of ETRTS testified:

Q. ...you would agree that – looked at – according to the criteria and everything, there's not a need for a new linear accelerator in Knoxville...right?

A. From a quantitative standpoint, I would agree with that.

Q. And one of the Guidelines for Growth criteria that applies in this case is that every linear accelerator should serve a population of at least 120,000, right?

A. Yes.

Q. And I understand you have issue – you don't really like that guideline very much, right?

A. I don't.

Q. But you agree that the project as proposed doesn't satisfy it, correct?

A. I would agree with that.

11. ETRTS attempted to discredit the analysis of Dr. Collier when she opined that there was no demonstrated need for a new LINAC by contending that she did not adequately take into account other demographic trends (population growth, aging population and high cancer rate) in the service area that would increase utilization in the future. Dr. Collier did in fact take those demographics into account but believed they are offset by other factors that will impact the utilization rate in the future. (Findings of Fact Nos. 16-17) Mr. Sullivan, testifying on behalf of ETRTS, conceded that earlier such projections for an increase in utilization rates would have been incorrect:

² It was not satisfactorily explained why the HSDA has continued to approve LINACs in this service area when the objective criteria found in the State Health Plan fails to demonstrate a need. Perhaps the guidelines should be modified or the HSDA rules should be amended to more clearly specify when it is appropriate to deviate from the criteria set forth in the State Health Plan.

Q. Sure. But if you had been – for example, if you had been hired by Provision back in 2009, you knew they filed an application for a CON back then, right?

A. They did.

Q. And if you had come in and told the Court or the Agency then, well, you think that radiation – demand for radiation therapy services is going to go up in the future, you would have been wrong, right?

A. I would have been.

Q. And, in fact, since that application was filed in 2009, we've seen two years of declining utilization, right?

A. We have.

12. The HSDA determined in 2009 there was no need for a new LINAC at Dowell Springs when it denied Provision's first CON application. (Finding of Fact No. 5) And as Dr. Collier stated, there has been a decline in the number of radiation treatments since that time. Indeed, the **only** factor positively impacting need that has changed in the Knoxville service area since 2009, is the approval of Provision's CON for a proton beam center in 2010. Despite Dr. Douglass's statement to the contrary before the HSDA in 2010 (Finding of Fact No. 7), ETRTS now contends that the introduction of the proton beam in 2014 makes a linear accelerator vital to the success of the proton beam therapy center as well as the other aspects of the Dowell Springs complex. This contention is simply not supported by the evidence. Dr. Douglass said as much himself before the HSDA in 2010. It was clearly established that a proton beam center can be successfully operated without an on-site LINAC, with some LINACs being located some 50 miles away from the proton center. (Findings of Fact Nos. 23-24) In this case, two LINACS are located within seven miles of Dowell Springs. A significant point of emphasis made by ETRTS in support of its contention that a LINAC is needed on-site to complement the proton beam

center is the high number of patients requiring combined or sequential therapy. However, it would appear that only 5-10% of the proton patients would require the use of a LINAC and those patients could easily receive their coordinated treatment from other area providers. (Finding of Fact No. 27)

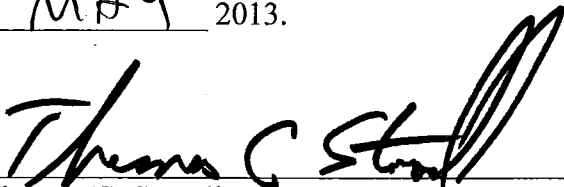
13. ETRTS also contended that a LINAC at Dowell Springs would provide a continuum of care and convenience for the patients seeking treatment from KCBC and TCS, two physician groups that have re-located their offices to the complex since 2008. As stated in Findings of Fact Nos. 28-29, this contention is not persuasive.

14. As previously stated, it appears that ETRTS has essentially attempted to “create a need” for this project where none exists. As the HSDA determined in 2009, and as agreed to by all parties, the guidelines of the State Health Plan do not show a need for a new LINAC in the service area. Nothing has changed in the service area since 2009, except the approval of the proton beam center and the number of radiation treatments has declined. Despite all the laudatory aspects of the Provision complex at Dowell Springs, the fact remains that there is no need for a new LINAC in the area and ETRTS cannot create a need by attaching this proposal to other facets of the Provision enterprise.

Conclusion


15. Covenant has carried its burden of proof by a preponderance of the evidence that the CON granted to ETRTS fails to meet the statutory and regulatory criteria for such action, specifically the requirement that there be a demonstrated need for the project. Accordingly, it is hereby **ORDERED** that the decision of the HSDA to grant the CON to ETRTS be **REVERSED** and the CON be **DENIED**.

This Order entered this 30TH day of MAY 2013.



Thomas G. Stovall
Administrative Judge

Filed in the Administrative Procedures Division, Office of the Secretary of State,
this 30TH day of MAY 2013.



Thomas G. Stovall, Director
Administrative Procedures Division

APPENDIX A TO INITIAL ORDER **NOTICE OF APPEAL PROCEDURES**

Review of Initial Order

This Initial Order shall become a Final Order (reviewable as set forth below) fifteen (15) days after the entry date of this Initial Order, unless either or both of the following actions are taken:

(1) A party files a petition for appeal to the agency, stating the basis of the appeal, or the agency on its own motion gives written notice of its intention to review the Initial Order, within fifteen (15) days after the entry date of the Initial Order. If either of these actions occurs, there is no Final Order until review by the agency and entry of a new Final Order or adoption and entry of the Initial Order, in whole or in part, as the Final Order. A petition for appeal to the agency must be filed within the proper time period with the Administrative Procedures Division of the Office of the Secretary of State, 8th Floor, William R. Snodgrass Tower, 312 Rosa L. Parks Avenue, Nashville, Tennessee, 37243. (Telephone No. (615) 741-7008). See Tennessee Code Annotated, Section (T.C.A. §) 4-5-315, on review of initial orders by the agency.

(2) A party files a petition for reconsideration of this Initial Order, stating the specific reasons why the Initial Order was in error within fifteen (15) days after the entry date of the Initial Order. This petition must be filed with the Administrative Procedures Division at the above address. A petition for reconsideration is deemed denied if no action is taken within twenty (20) days of filing. A new fifteen (15) day period for the filing of an appeal to the agency (as set forth in paragraph (1) above) starts to run from the entry date of an order disposing of a petition for reconsideration, or from the twentieth day after filing of the petition, if no order is issued. See T.C.A. §4-5-317 on petitions for reconsideration.

A party may petition the agency for a stay of the Initial Order within seven (7) days after the entry date of the order. See T.C.A. §4-5-316.

Review of Final Order

Within fifteen (15) days after the Initial Order becomes a Final Order, a party may file a petition for reconsideration of the Final Order, in which petitioner shall state the specific reasons why the Initial Order was in error. If no action is taken within twenty (20) days of filing of the petition, it is deemed denied. See T.C.A. §4-5-317 on petitions for reconsideration.

A party may petition the agency for a stay of the Final Order within seven (7) days after the entry date of the order. See T.C.A. §4-5-316.

YOU WILL NOT RECEIVE FURTHER NOTICE OF THE INITIAL ORDER BECOMING A FINAL ORDER

A person who is aggrieved by a final decision in a contested case may seek judicial review of the Final Order by filing a petition for review in a Chancery Court having jurisdiction (generally, Davidson County Chancery Court) within sixty (60) days after the entry date of a Final Order or, if a petition for reconsideration is granted, within sixty (60) days of the entry date of the Final Order disposing of the petition. (However, the filing of a petition for reconsideration does not itself act to extend the sixty day period, if the petition is not granted.) A reviewing court also may order a stay of the Final Order upon appropriate terms. See T.C.A. §4-5-322 and §4-5-317.

**BEFORE THE TENNESSEE
HEALTH SERVICES AND DEVELOPMENT AGENCY 2012 JUN 13 PM 12: 12
NASHVILLE, TENNESSEE**

IN RE:)	
)	Docket No. 25.00-115208J
EAST TENNESSEE RADIATION)	
THERAPY SERVICES LLC)	CON no. CN 1108-030
CN 1108-030A)	

**EAST TENNESSEE RADIATION THERAPY SERVICES LLC'S
PETITION FOR AGENCY REVIEW OF
ADMINISTRATIVE JUDGE'S ORDER DENYING A CON**

Pursuant to Tenn. Code Ann §§ 4-5-315 and 68-11-1610, Respondent East Tennessee Radiation Therapy Services LLC ("ETRTS") respectfully requests that the Agency review and reverse the Initial Order entered in this contested case proceeding on May 30, 2013. The Initial Order denies the Certificate of Need ("CON") at issue in this proceeding, which the Health Services & Development Agency ("HSDA" or "Agency") had previously voted to approve in December 2011.

RELEVANT PROCEDURAL HISTORY

1. On August 15, 2011, ETRTS filed a CON application with HSDA seeking permission to initiate conventional radiation therapy services using a single linear accelerator located at the Dowell Springs medical campus in central Knoxville.

2. The application was opposed by, among others, Covenant Health ("Covenant"), which owns and operates the dominant hospital system in and around Knoxville. Covenant also is the dominant provider of radiation therapy services in the service area. Covenant owns and operates 8 of the 15 linear accelerators located in the service area, and, as of 2011, it had a nearly 54% market share for radiation therapy treatments. Discovery in this matter has revealed that,

despite this market dominance, Covenant executives determined to oppose the ETRTS CON application days before it was even filed and within one hour of learning of ETRTS's notice of intent to file.

3. The CON application underwent extensive review by staff at both the HSDA and the state Department of Health, including at least two sets of supplemental questions from the HSDA, to which ETRTS responded with nearly 75 pages of additional information. The CON application received wide support, including the support of a former chairman of the HSDA and the director of radiation oncology at the University of Tennessee Medical Center.

4. The HSDA considered the ETRTS application at its regular meeting on December 14, 2011. The hearing on the ETRTS project lasted approximately three hours. Covenant was allotted more than 30 minutes – three times the standard time limit for opposition presentations – to make its opposition presentation. At the conclusion of the presentations, the members of the HSDA questioned representatives of both ETRTS and Covenant for more than an hour before engaging in an extensive discussion among themselves about the pros and cons of the ETRTS project. At the end of that discussion, a majority of the Agency members voted to approve the CON application.

5. On December 22, 2011, Covenant filed its petition for contested case hearing with the HSDA. Of the four major providers of radiation therapy services in the service area, Covenant was the only provider to contest the Agency's decision to approve the CON for the ETRTS project.

6. After extensive pre-hearing discovery, the hearing of the contested case began on January 14, 2013 before Administrative Law Judge Thomas G. Stovall (the "ALJ"). The hearing

of the contested case concluded on January 29, 2013, following eight days of testimony and argument.

7. On May 30, 2013, the ALJ entered an Initial Order denying the CON granted to ETRTS and, thus, effectively reversed the Agency's previous decision to grant the CON.

8. In his Initial Order, the ALJ found that the economic feasibility of the ETRTS project was "without question." *See* Initial Order at 16. Indeed, according to the ALJ, "it is uncontested by the parties that this project can be economically accomplished and maintained." *Id.* at 22.

9. The ALJ also concluded in his Initial Order that the ETRTS project would contribute to the orderly development of healthcare. According to the ALJ, the ETRTS project and other initiatives underway on the Dowell Springs campus "will benefit not only Knoxville but the entire southeastern United States." *See id.* at 21. These initiatives include "collaborative research and educational projects" that the ALJ said "are to be encouraged and may hopefully result in advancements in cancer treatment and medical education." *See id.* at 22. Importantly, the ALJ made clear that "[t]he proof in this case *did not establish* that the ETRTS linear accelerator would negatively impact the orderly development of healthcare in the service area." *See id.* (emphasis added). With respect to Covenant in particular, the ALJ found that any loss in revenue at Covenant attributable to competition from ETRTS "should not have a significant negative impact on [Covenant's] viability" in light of Covenant's "overall financial strength." *Id.* at 18.

10. In deciding the issue of need, however, the ALJ adhered strictly to the numerical benchmarks set out in the HSDA's *Guidelines for Growth*. Based on that strict adherence, the ALJ concluded that "[d]espite all the laudatory aspects of the Provision complex at Dowell

Springs, the fact remains that there is no need for a new [linear accelerator] in the area” *See id.* at 26. Significantly, in stating this conclusion, the ALJ expressed dissatisfaction about “why the HSDA has continued to approve [linear accelerators] in this service area when the objective criteria found in the State Health Plan fails to demonstrate a need.” *Id.* at 24 n. 2.

REASONS TO ACCEPT REVIEW

The Agency should exercise its authority under Tenn. Code Ann. §§ 4-5-315 and 68-11-1610 to review and reverse the ALJ’s Initial Order and grant the CON to ETRTS for, at a minimum, the following reasons.

1. As noted above, the ALJ’s Initial Order reversing the previous decision to grant a CON to ETRTS rests on the conclusion that the *Guidelines for Growth* impose mandatory benchmarks that do not allow for the approval of a CON unless all of the relevant benchmarks are satisfied. According to the ALJ, even though the ETRTS project is “laudatory,” is “without question” economically feasible, will “not have a significant negative impact” on Covenant and “will benefit not only the Knoxville area but the entire southeastern United States,” the CON for the project must nevertheless be denied because it “does not meet the objective criteria set forth in the State Health Plan to justify the addition of a new [linear accelerator] in the market.” *See* Initial Order at 16, 18, 21 and 23. Moreover, according to the Initial Order, in order for the HSDA “to deviate from the criteria set forth in the State Health Plan,” it will be necessary to amend the State Health Plan and/or the HSDA rules. *See* Initial Order at 24 n.2.

2. In this respect, the ALJ’s Initial Order misapplies existing law and stands in sharp contravention of the Agency’s long-standing practice in reviewing CON applications. Indeed, it is well established that, as a matter of law and sound public policy, the numerical benchmarks set out in the *Guidelines for Growth* are not mandatory, and that the Agency can depart from those

Guidelines in approving or denying a CON. “Pursuant to Tenn. Code Ann. § 68-11-1609(b), the *Guidelines* are not mandatory but should be merely used as a guide.” *In the Matter of Spring Hill Hosp., Inc.*, Docket No. 25.00-092967J, Initial Order dated Oct. 12, 2007 at 32. The health planning experts who testified, respectively, for ETRTS and Covenant at the hearing in this contested case were in complete agreement on this point. As ETRTS will explain more fully in subsequent briefing of this issue, the Agency should act to correct the ALJ’s misconception about the HSDA decision-making authority and discretion when considering and balancing all of the facts relevant to a CON application.

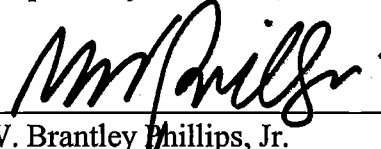
3. The ALJ’s Initial Order also fails to address a number of extremely significant facts in the record, and the findings of fact in the Initial Order indicate that the ALJ either misunderstood or misapplied other important facts. Those facts, which ETRTS will enumerate more fully in future briefing, go directly to the unique circumstances – including circumstances highlighted by members of the Agency during discussion of the application in December 2011 – that make the numerical benchmarks set out in the *Guidelines for Growth* less relevant to the evaluation and approval of this particular CON. By either ignoring or misconstruing critical facts relating to the need for ETRTS, the Initial Order ultimately is not supported by the substantial and material evidence in the record and should be reversed.

CONCLUSION

For the foregoing reasons, ETRTS respectfully requests that the Agency accept review of the ALJ’s Initial Order dated May 30, 2013, and that the Agency place this matter on the agenda to be considered at its earliest opportunity.

DATED this 13th day of June, 2013.

Respectfully submitted,



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CERTIFICATE OF SERVICE

I hereby certify that, on June 13, 2013, a true and correct copy of the foregoing was served via electronic mail and/or U.S. Mail upon the following:

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